

REMARKS

Claims 1, 2, 4-43, 45-50, 52-63, 65-70, 72-74 and 76-80 are pending in the present application. Claims 11-24, 27-43, 46-50, 52-56, 65-70, 72-74 and 76-80 are withdrawn from consideration. Claims 1, 2, 4-10, 25, 26, 45, and 57-63 are rejected. Claims 1, 25, 26, and 45 have been amended. Claims 2 and 57-63 are herein cancelled. Claim 81 has been added as a new claim. No new matter has been added by way of amendment. The present response is an earnest effort to place all claims in proper form for immediate allowance. Reconsideration and passage to issuance is therefore respectfully requested.

Interview Summary

Applicants thank the Examiner for granting an interview with Applicants on June 18, 2007. Applicants have reviewed the Interview Summary and Continuation Sheet including the description of the Substance of Interview and believe it accurately describes the substance of the interview.

Detailed Action

A. Specification and Sequence Listing

Applicants acknowledge the Examiner's statement that the previous objection to the specification for containing browser executable code is withdrawn. Applicants further acknowledge the Examiner's statement that the bases for the sequence presented as SEQ ID NO: 23 can be found in originally filed SEQ ID NO: 7, as well as FIG. 7 of the originally filed specification.

Claim Rejections

A. 35 U.S.C. § 112, 2nd paragraph

Claims 2 and 63 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Regarding claim 2, the Examiner states the claim is "unclear over the recitation of the phrase 'said polymorphism is selected from the group consisting of: a single nucleotide polymorphism (SNP), a deletion, and an insertion' because claim 1, from which claim 2 depends,

specifies identification of a thymidine at position 3832, which is a single nucleotide polymorphism.”

Although not acceding to the Examiner’s rejection, in an effort to expedite prosecution, Applicants have canceled claim 2, thereby alleviating this rejection.

Regarding claim 63, the Examiner states the “the marker” is unclear because there is no antecedent basis for the recitation.

Although not acceding to the Examiner’s rejection, in an effort to expedite prosecution, Applicants have canceled claim 63, thereby alleviating this rejection.

With regard to the Examiner’s rejection of claim 45, the Examiner states that “[t]he rejection of claim 45 over recitation of the phrase ‘favorable traits associated with reproductive longevity’ has been withdrawn.” The Examiner further states that “[h]owever, the breadth of the claim is noted. . . . while the claim defines ‘reproductive longevity potential’, the claim requires screening for traits ‘associated with’ reproductive longevity potential, and does not in fact require screening for reproductive longevity potential.” The Examiner maintains the rejection of claim 45.

Although not acceding to the Examiner’s rejection, in an effort to expedite prosecution, Applicants have amended claim 45 to recite in part “favorable reproductive longevity potential traits”. Applicants therefore submit claim 45 is in condition for allowance.

In light of the above remarks, Applicants respectfully request reconsideration and withdrawal of the rejections to claims 2, 45 and 63 under 35 U.S.C. § 112, second paragraph.

B. 35 U.S.C. § 112, 1st paragraph, Written Description

Claims 25 and 26 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that the claim(s) contains subject matter, which was not described in the specification in such a way as reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner further states “[t]he claims are broadly drawn to any polymorphic variant of an IGF-1R gene (e.g. splice variants, polymorphisms and mutations including single and multiple nucleotide substitution, insertions, deletions, translocations and gene rearrangements) comprising any genotype at position 3832 of SEQ ID

NO: 23, which thus encompasses any variants such as SNPs, and deletions and insertions of any number of nucleotides of any sequence.”

Applicants respectfully traverse this rejection. In order to expedite prosecution, Applicants have amended independent claim 25. As amended, claim 25 now recites “assaying for the presence of a polymorphism in an IGF-1R gene corresponding to position 3832 of SEQ ID NO:23, wherein said polymorphism is a thymidine at position 3832 of SEQ ID NO: 23, said polymorphism being associated with reproductive longevity potential, wherein the trait of reproductive longevity potential is characterized by an increase in the number of pregnancies or the duration of time a pig is capable of reproduction relative to the mean of a given population, group or species”.

Applicants' claimed invention relates to the association of the IGF-1R gene to the phenotypic traits of reproductive longevity potential. Thus, each species within the genus encompassed by Applicants' claims all share the common attribute of being a genetic loci that has a measurable effect on these phenotypic traits.

The structural feature common to all members of the genus is the IGF-1R gene. Further, in order to fall within the scope of Applicants invention, the variant screened for within the IGF-1R gene, or a region therein, must have the function of being associated with reproductive longevity potential. The specification teaches at least one polymorphism that has been identified which correlates with a phenotypic difference in reproductive longevity potential. This polymorphism is identified in the specification by a C/T nucleotide substitution at position 3832 in the IGF-1R gene. See specification, Example 3, pages 55-56; Figure 7. One of skill in the art would recognize that Appellant's were in possession of the common attribute within the genus, i.e., the association between the IGS-1R gene and the phenotypic traits of reproductive longevity potential.

In light of the above remarks and amendments, Applicants respectfully request reconsideration and withdrawal of the rejections to claims 25 and 26 under 35 U.S.C. § 112, first paragraph.

C. Claim Rejections Under 35 U.S.C. § 112, 1st Enablement

Claims 1, 2, 4-10, 25, 26, 45, 57-63 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner states that “[t]he specification

is not enabling for methods of analyzing the reproductive longevity of a pig comprising assaying for the presence of a polymorphism in the IGF-1R gene at position 3832 of SEQ ID NO: 23". The Examiner further states, in the Response to Applicants' Remarks from the Amendment filed December 20, 2006, that "it is noted that claims 1, 2, 4-10, 25, 26, and 45" do not require detection of homozygosity of the '2' allele (i.e. T at 3832 of SEQ ID NO: 23)."

Applicants respectfully traverse this rejection. However, in an effort to expedite prosecution, Applicants have amended independent claims 1, 25 and 45 and canceled claims 57-63. As amended, each of the independent claims recites assaying or detecting a polymorphism, the polymorphism being in the IGF-1R gene corresponding to position 3832 of SEQ ID NO: 23, "wherein said [the] polymorphism is a thymidine at position 3832 of the SEQ ID NO: 23, said [the] polymorphism being associated with [predictive of the pig having] reproductive longevity potential, wherein the trait of reproductive longevity potential is characterized by an increase in the number of pregnancies or the duration of time a pig is capable of reproduction relative to the mean of a given population, group or species".

The Specification is fully enabling for the claimed methods. Applicants teach that variation in the IGF-1R gene is associated with reproductive longevity potential. The Specification identifies a specific polymorphism that exists within the IGF-1R gene which allows one skilled in the art to select those pigs which are likely to produce these desired traits (Specification, Example 3, pp. 55-56).

To support these statements and in response to this rejection, Applicants are submitting a Declaration of Dr. Alan Mileham under 37 U.S.C. § 1.132. The Examiner has objected to the accuracy of the P-values contained in the first analysis (titled "Samples from old surviving sows and from young sows culled during the first 4 parities") in Example 3. The Examiner states "while applicants argue that the p-values of the first analysis (using 996 sows) are accurate, the specification indicates that the effect on parities is 'overestimated due to the data structure'". Applicants traverse this statement. Dr. Mileham's Declaration describes the procedure used in the first analysis of Example 3. 996 sows (972 were successfully genotyped) from four different farms were genotyped and tested for the effect of SNP 3832 on the number of parities. Samples from old surviving sows and from young sows culled during the first 4 parities were used (see figure x1 in Dr. Mileham's Declaration, paragraph. 6). As illustrated in figure x1 of Dr. Mileham's Declaration, selective genotyping scheme was used in this study, meaning that the

high and low extremes of the population were genotyped. When using a selective genotyping scheme, the marker effects are usually overestimated. However, the significance levels (P-values) are correct. Therefore, while it would be expected that the marker effect would be smaller than the 1.11 parities per allele, the P-value of 0.004 is still accurate and highly significant.

Regarding the second analysis of Example 3 (titled "Germany (GER): Longevity (reproduction) data from sows with known pedigree with DNA samples from their sires"), the Examiner states "that the provided p-value of $P=0.062$ is not sufficient to consider the results 'statistically significant'". In response to this rejection and statement, Applicants are submitting Dr. Mileham's Declaration. Dr. Mileham's Declaration contains data and results from the most recent analysis regarding longevity (reproduction) data from sows with known pedigree with DNA samples from their sires. The most recent analysis was performed in August 2007 and was conducted by including all available sires that had over 10 daughters and using their most updated phenotypes. Data from 239 sires was used (with records on over 51,000 daughters), 139 of which were line L02 and 100 of which were from L03. Genotypes were collected on the sires, and the phenotype was the sire's estimated breeding value (EBV) for their daughters' age at culling, for sires from L02 and L03. Sires used in the trial had to have at least 10 daughters that completed their lifetime production. The completion of a lifetime production is defined as the daughters either died or were culled. As the experimental design is defined, it is expected that more sires will become available overtime and that the phenotypes (EBV) of old and new sires will continue to change as more siblings and relatives enter and leave the production cycle and affect the sire's EBVs. Therefore repeated analysis using the most recent phenotypes is expected to differ from previous analysis. A significant dominant effect of SNP 3832 was demonstrated in line L02. The '12' genotype had the highest culling-age with dominant effect of 18.9 days and p-value of $P=0.053$. While in L03 the marker had no significant additive ($p=0.550$) or dominant ($p=0.832$) effects, the lack of consistency between L02 and L03 in this study is not an uncommon occurrence. The fact that different single nucleotide polymorphisms (SNPs) (within the same gene or in different genes) have different effects in different breeds, lines or crosses tends to be the rule rather than the exception, and does not negate the value of this marker when used with appropriate sampling. Accordingly, Applicants have provided additional results which

demonstrate that a statistically significant association exists between the thymidine polymorphism at position 3832 of the SEQ ID NO: 23 and days to culling.

In light of the above remarks, Applicants respectfully requests reconsideration and withdrawal of the rejections to claims 1, 2, 4-10, 25, 26, 45, 57-63 under 35 U.S.C. § 112, first paragraph.

D. 35 U.S.C. § 102

Claims 57 and 63 are rejected under 35 U.S.C. § 102(b) as being anticipated by Harumi et al. The Examiner states “Harumi et al. teaches the detection of the required nucleotide content at the required position of the pig IGF-1R gene.”

Although not acceding to the Examiner’s rejection, Applicants have canceled claims 57-63, thereby alleviating this rejection. Applicants respectfully request the Examiner withdraw the rejections to claims 57 and 63 under 35 U.S.C. § 102(b) as being anticipated by Harumi et al..

Conclusion

Please consider this a Request for a Three-Month Extension of Time from June 26, 2007 to September 26, 2007 and charge Deposit Account No. 26-0084 the amount of \$1,020.00 for this extension.

Please also charge Deposit Account No. 26-0084 the amount of \$250.00 for one new claim over 20 and one new independent claim over 3.

No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Hodgson', with a long horizontal flourish extending to the right.

ROBERT A. HODGSON, Reg. No. 56,375
McKEE, VOORHEES & SEASE, P.L.C.
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No: (515) 288-3667
Fax No: (515) 288-1338
CUSTOMER NO: 22885

Attorneys of Record

- RAH/bjh -

Enclosure: Declaration